Drug Package Leaflets: Information on Side Effects Confuses Patients

Online study shows that additional information could help

Berlin, 17 October 2018 – The descriptions of side effects given in the package leaflets supplied with medication are often difficult for patients to understand. According to an online study conducted by the Max Planck Institute for Human Development in Berlin and the University of Hamburg with almost 400 lay participants, a small addition could help. The findings have been published in the journal *PLOS ONE*.

Before taking any medication, it is important to read the package leaflet to find out how to take the medication and learn about possible side effects. But information on side effects is often difficult to understand—primarily because no comparative information is given on how often the undesired symptoms occur in people taking the medication as opposed to in people not taking it. Such comparative data are not currently provided in package leaflets in Germany or other European countries.

"Very few people know that there is not necessarily a causal connection between the symptoms listed as side effects and the medication taken. In a previous study, we showed that even doctors and pharmacists misinterpret the listed frequencies of side effects as being caused solely by the drug," says lead author Viktoria Mühlbauer, pharmacist and doctoral candidate at the University of Hamburg.

The aim of the latest study was to investigate whether alternative package leaflets that include comparative information would reduce these misinterpretations. In an online study, 397 participants were each shown one of four package leaflets. All leaflets listed the same four undesired symptoms (side effects). Three of the four leaflets listed the frequency of each symptom with and without drug intake and explained the causal relation between the listed frequency of side effects and drug intake. The fourth corresponded to the standard package leaflet currently supplied, and only reported the frequency of symptoms with drug intake.

Participants who had read one of the alternative package leaflets did much better in a subsequent assessment. Whereas only two to three percent of participants who had read the standard leaflet were able to correctly answer questions on the causal nature of side effects, up to 82 percent of those who had read an alternative leaflet did so. In other words, the alternative leaflets were less misleading. "The fact that the information formats used in the healthcare system confuse both patients and doctors is a major problem that threatens patient and drug safety," says senior author Odette Wegwarth, researcher in the Center for Adaptive Rationality at the Max Planck Institute for Human Development. She adds that there is now a strong body of evidence showing which information formats support patients and doctors in understanding the benefits and harms of medical interventions—and which do not. "What we need to translate these findings into real-world change is concerted commitment and effort on the part of all relevant stakeholders in the healthcare system," says Wegwarth.

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